



651 Gateway Boulevard, Suite 1145  
South San Francisco, CA 94080  
Phone – 650.871.7101  
Fax – 650.871.7555  
[www.baybio.org](http://www.baybio.org)

**Caitlyn Waller**  
Acting President

*Chair*

**Michael Arbige, Ph.D.**  
Genencor International

**Gregg H. Alton**  
Gilead Sciences  
**Walter T. Anderson, Ph.D.**  
Futurist and Environmental Author  
**Robert M. Berdahl, Ph.D.**  
University of California at Berkeley  
**J. Michael Bishop, M.D.**  
University of California at  
San Francisco  
**Mina J. Bissell, Ph.D.**  
Lawrence Berkeley National Laboratory  
**Warren S. Browner, M.D., MPH**  
CA Pacific Medical Center Research  
Institute  
**Mildred K. Cho, Ph.D.**  
Center for Biomedical Ethics  
Stanford Univ. School of Medicine  
**Bryan Croeni, AIA**  
MBT Architecture, Inc.  
**Brian C. Cunningham, Esq.**  
Formerly of Rigel Pharmaceuticals  
**A. Stephen Dahms, Ph.D.**  
California State Universities  
Program for Education & Research in  
Biotechnology  
**Frederick J. Dorey, Esq.**  
Cooley Godward LLP  
**Hon. Joseph A. Fernekas**  
City of South San Francisco  
**Hon. Daniel Furtado, Pharm.D.**  
City of Campbell  
**Tom A. Glaze**  
Metabolex  
**Russell C. Hirsch, M.D., Ph.D.**  
Prospect Venture Partners  
**Peter Hirth, Ph.D.**  
Plexxikon, Inc.  
**Todd Kaufman**  
Genentech, Inc.  
**David W. Martin**  
Eos Biotechnology  
**Scott W. Morrison**  
Ernst & Young LLP  
**Lynn H. Pasahow**  
Fenwick & West LLP  
**Daniel Perez, M.D.**  
Berlex Biosciences  
**A. Franklin Rice**  
VistaGen, Inc.  
**George A. Scangos, Ph.D.**  
Exelixis Pharmaceuticals  
**William R. Srigley**  
AltaGen Bioscience, Inc.  
**Larry N. Vanderhoef, Ph.D.**  
University of California at Davis  
**William D. Young**  
ViroLogic, Inc.

July 17, 2003

OSWER Docket  
EPA Docket Center  
Environmental Protection Agency  
Mailcode: 5305T  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Re: Docket ID No. RCRA-2003-0012

Dear Sir or Madam:

The Bay Area Bioscience Center (BayBio) and the Palo Alto Environmental Health & Safety Forum would like to thank the US Environmental Protection Agency (EPA) for this opportunity to submit comments on the Management of Hazardous Waste in Research and/or Academic Laboratories.

This is a key issue to our group's members, who represent the bioscience, medical and high-tech industries and academic institutions operating in Northern California. As global competition increases in all of these fields, there is a need for an effective and cost-efficient approach to the management of hazardous wastes from industrial and academic laboratories in the U.S. It is difficult, inefficient and costly for laboratories to comply with RCRA regulations in their current form, which were designed for large industrial processes. The current regulatory approach can actually constrain efforts by laboratories to promote environmental stewardship through programs of reduction, reuse and recycling.

Both BayBio and the Palo Alto Environmental Health & Safety Forum support an integrated, flexible and performance-based approach for managing lab-generated hazardous waste. This type of approach is being modeled and described in the EPA's New England Universities Laboratories Project XL and EPA's Howard Hughes Medical Institute's Collaborative Hazardous Waste Management Project. In these projects, there is a great deal of flexibility given to a laboratory based on site-specific conditions in addressing issues such as:

- Location of the hazardous waste determination
- Hazardous Waste training for lab personnel
- Hazardous Waste Labeling
- Waste accumulation and storage time periods
- Laboratory treatment of hazardous waste

In addition, both organizations support a broad definition of the term "laboratory" to ensure that all types of applicable laboratories are included in any new approach developed by the EPA. This broad definition needs to include R&D laboratories associated with industry, such as Quality Assurance Labs, Pilot Plant Labs, Process Science Facility Labs and labs in production areas. These laboratories face the same challenges as the more conventional R&D laboratories do in managing hazardous waste.

*Chair emeritus*

**Ronald E. Cape, Ph.D.**  
Biotechnology Investor

*Director emeritus*

**G. Steven Burrill**  
Chief Executive Officer, Burrill & Company

*Director emeritus*

**Edward E. Penhoet, Ph.D.**  
Senior Director, Gordon and Betty Moore Foundation

July 17, 2003  
Page 2

BayBio's mission and purpose is to strengthen Northern California's climate for bioscience research, development, and commercialization through public policy, education and outreach. BayBio acts as the bridge to the bioscience community, sharing information about the world's largest bioscience cluster and its distinct needs. BayBio has over 180 members, including Applied Biosystems, Alza, Bayer, Chiron, Genencor, Genentech, Gilead Sciences, Stanford University, University of California Lawrence Berkeley National Laboratory and University of California at San Francisco.

The Palo Alto Environmental Health & Safety Forum is a consortium of environmental, health and safety professionals from private industry and academia which meets monthly, under the auspices of the Palo Alto, California Chamber of Commerce, to discuss regulatory compliance issues. Participants in the Forum include Stanford University, Stanford Medical Center, Roche Bioscience, Hewlett-Packard, Agilent Technologies, Lockheed, Genencor, Varian Medical Systems, DNAX, dpiX, Xerox PARC, Incyte Genomics and SRI International.

The attached comments on the Management of Hazardous Waste in Research and/or Academic Laboratories reflect the thinking and experience of world leaders and cutting edge organizations in biotech, high-tech and academia.

Please contact us if you have any questions or comments on the material submitted and thank you again for the opportunity to comment on this important topic.

Sincerely,

Caitlyn Waller  
Acting President  
Bay Area Bioscience Center

Denise Kato  
Chair  
Palo Alto EHS Forum

**Bay Area Bioscience Center  
EH&S Working Group & Palo Alto EHS Forum  
Comments on  
USEPA Management of Hazardous Wastes  
In Research and/or Academic Laboratories  
Page 1**

**Issue: Hazardous Waste Determination**

**Question 1: When should the hazardous waste determination be made in a laboratory setting?**

The company or institution managing the laboratory, based upon the specific conditions at the site, should decide the location of the hazardous waste determination. Current regulations should be revised to provide laboratories flexibility in determining where the on-site hazardous waste determination is made, as long as the determination is made prior to transporting the waste to an off-site location. This approach is supported by both the EPA's Howard Hughes Medical Institute's Project on Best Practices for Managing Hazardous Wastes in Academic Research Institutions and EPA's New England Labs XL Project.

For some small laboratories, hazard waste determination in the laboratory makes sense given the process flow of the laboratory, the amount of waste generated and the manpower available. For a small laboratory producing limited quantities of the same type of hazardous waste on a routine basis, it may be most efficient for laboratory personnel to make the determination and oversee the proper disposal of the waste material.

For larger industrial and academic institutions with multiple laboratories at a location, the regulations should allow the hazardous waste determination to be made at an on-site hazardous materials/waste management facility. This approach would allow for the timely and efficient collection of used and unused chemicals from laboratories. The chemicals could then be brought to a central facility for efficient processing, hazardous waste determination and the selection of the most appropriate management option by trained EHS personnel (trained in Federal and state hazardous waste regulations including waste determination, land ban restrictions, etc.). These management options could include reuse, recycling, consolidation, storage, volume reduction, treatment and disposal. In this way, laboratory chemicals are managed in an environmentally responsible manner, while providing the company or institution the opportunity to reduce disposal costs by employing a number of different chemical management options.

**Bay Area Bioscience Center  
EH&S Working Group & Palo Alto EHS Forum  
Comments on  
USEPA Management of Hazardous Wastes  
In Research and/or Academic Laboratories  
Page 2**

**Question 2: What training is needed for lab personnel concerning hazardous waste determinations (e.g., full RCRA training or training that is made specific to chemical management duties)?**

Laboratory personnel should be trained based on their specific role in the business or institution's hazardous materials/waste program. In other words, with regard to hazardous materials/waste, what are the laboratory personnel's chemical management duties and what do they need to know to manage these materials in a responsible manner. They should be trained to the appropriate level of their responsibility and duties.

In a small laboratory, in which lab personnel are making the hazardous waste determination and managing waste disposal, they need to be trained to understand the applicable Federal and state hazardous waste regulations. But this approach makes no sense in a large facility where trained EHS personnel are conducting the hazardous materials/waste management at a central facility. In this case, it is an inefficient use of laboratory personnel's time to train them in the details of RCRA regulations and hazardous waste determination when it is not part of their duties. The detailed training is better focused on appropriate members of the EHS staff who regularly manage the site's hazardous materials/wastes. Laboratory personnel would receive training in the OSHA Laboratory Standard, the Hazard Communication Standard and any site-specific training deemed necessary by the EHS Department.

**Question 3: How should waste be labeled so that it can be appropriately managed as hazardous waste (e.g., the words "hazardous waste" or a detailed chemical description)?**

Laboratory personnel should be required to label any used or unused chemicals (unwanted or surplus materials) that will be leaving the laboratory with a description that includes adequate information to allow for a hazard assessment and a hazardous waste determination to be made.

In a small laboratory, in which lab personnel are making the hazardous waste determination and managing waste disposal, they would use the information label to make the determination. If the chemical were determined to be a hazardous waste

**Bay Area Bioscience Center  
EH&S Working Group & Palo Alto EHS Forum  
Comments on  
USEPA Management of Hazardous Wastes  
In Research and/or Academic Laboratories  
Page 3**

by laboratory personnel, then the appropriate hazardous waste label would be attached.

For larger industrial and academic institutions with multiple laboratories at a location, the information label would be attached prior to removing the material from the laboratory and transporting it to the on-site hazardous materials/waste management facility. The information label would allow EHS personnel to take appropriate precautions in transport. Once the material arrived at the on-site hazardous materials/waste management facility, the information could be used to make the hazardous waste determination and select the best management option for the chemical in question. This would allow EHS personnel to label chemicals as hazardous waste only after all possible reuse options have been eliminated.

**Question 4: Where should the hazardous waste determination be made (e.g., on the bench or in the 90 to 180 day storage area)?**

See response to Hazardous Waste Determination Question No. 1.

**The company or institution managing the laboratory, based upon the specific conditions at the site, should decide the location of the hazardous waste determination. Current regulations should be revised to provide laboratories flexibility in determining where the on-site hazardous waste determination is made, as long as the determination is made prior to transporting the waste to an off-site location. This approach is supported by both the EPA's Howard Hughes Medical Institute's Project on Best Practices for Managing Hazardous Wastes in Academic Research Institutions and EPA's New England Labs XL Project.**

**Issue: Satellite Accumulation Area (SAA) Accumulation Time: If more than 55 gallons of hazardous waste or more than 1 quart of acute hazardous waste is accumulated at a SAA, the excess must be removed within three days.**

**Question 1: How should these requirements be applied in a laboratory context?**

**Storage and accumulation requirements for hazardous and acute hazardous waste at SAAs should be determined by the specific conditions at the company or**

**Bay Area Bioscience Center  
EH&S Working Group & Palo Alto EHS Forum  
Comments on  
USEPA Management of Hazardous Wastes  
In Research and/or Academic Laboratories  
Page 4**

**Institution.** These conditions include the chemical hazard, the nature of the laboratory work and the amount of storage space available. Accumulation time limits and volume storage limits for laboratories could be spelled out in the site's Environmental Management Plan, as it is for Boston College under EPA's New England Labs XL Project. The three-day time limit for removal is too short to allow for effective and cost-efficient collection of waste and longer time periods need to be allowed, as they under EPA's New England Labs XL Project.

**Question 2:** How often do laboratories accumulate more than 55 gallons of waste in their SAA?

Generally, it is unusual for labs to generate more than 55 gallons of used or unwanted hazardous material/waste at an SAA over a short time period. As stated above, it is not a waste until all possible reuse management options have been eliminated and the hazardous waste determination has been made. But under certain situations, this amount of accumulation can occur, and longer accumulation time periods and greater volume storage requirements are needed to efficiently manage hazardous waste under these conditions.

**Question 3:** What, if any, difficulties do environmental, health and safety personnel have responding to waste pick-up calls, e.g., within the three-day time limit?

The three-day response requirement does not allow the most effective and cost-efficient use of EHS staff. Under the current three-day time limit, decisions on the priority of hazardous material/waste pick-up from laboratories may be made on the basis of the regulatory requirement, rather than on the true nature of the chemical hazard, the need of the laboratory or the most efficient use of staff resources.

**Question 4:** How would a longer time frame for removal impact the cost of waste management and the ability to protect human health and the environment?

Costs of waste management would be reduced because businesses and institutions could make more efficient use of EHS personnel in managing material/waste pick-

**Bay Area Bioscience Center  
EH&S Working Group & Palo Alto EHS Forum  
Comments on  
USEPA Management of Hazardous Wastes  
In Research and/or Academic Laboratories  
Page 5**

ups because schedules would be based on the chemical hazard or need of the laboratory, rather than on an arbitrary regulatory requirement.

There would be no impact on the protection of human health and the environment by allowing longer time periods for the removal of hazardous materials/wastes from laboratories. No matter the allowable accumulation time period permitted by the regulations, laboratories are required under the OSHA Lab Standard to manage chemicals at all time to protect employee health and safety, as specified in a site's Chemical Hygiene Plan. Longer accumulation times would have no impact on the ability to protect the environment because waste would still be properly stored, transported and disposed of in compliance with all applicable Federal and state regulations.

**Issue: Treatment in SAA's:** We have heard from numerous stakeholders that they would like to perform certain types of treatment.

**Question 1: What types of treatment, other than neutralization, are laboratory  
Personnel currently performing or would like to perform?**

EPA should allow for scientifically sound treatment of small quantities of hazardous waste generated in laboratories as a means of increasing human health and safety, enhancing protection of the environment and reducing transportation and disposal costs.

Laboratory personnel are often interested in deactivating reactive chemicals to make the unwanted hazardous material less hazardous or easier to handle and transport. Under certain Department of Transportation regulations that require highly specialized requirements for handling and transport, stabilization for transport can be important. It can assist in better protecting health and safety and the environment and greatly reduce transportation and disposal costs. In addition, some laboratories practice recovery of solvents through distillation. This reduces the amount of hazardous waste transported off-site, with all of the associated risk factors, and correspondingly reduces the site's hazardous waste disposal costs.

**Bay Area Bioscience Center  
EH&S Working Group & Palo Alto EHS Forum  
Comments on  
USEPA Management of Hazardous Wastes  
In Research and/or Academic Laboratories  
Page 6**

**Question 2: What would be the benefits of the desired types of treatment?**

The benefits of permitting scientifically sound laboratory or “bench top” treatment of hazardous wastes by laboratory personnel would be:

- Reduction of the inherent hazard of the material no longer wanted by the laboratory,
- Recovery of the material for reuse in the laboratory, and
- Reduction in hazardous waste disposal costs.

**Other Issues:**

**Definition of Laboratory**

Both the Bay Area Bioscience Center and the Palo Alto EHS Forum support a broad definition of “laboratory” to ensure that all types of applicable laboratories are included in any new regulatory approach developed by EPA. This broad definition needs to include R&D laboratories associated with industry such as Quality Assurance Labs, Pilot Plant Labs, Process Science Facility Labs and labs in production areas. These laboratories face the same challenges as more conventional R&D laboratories in managing hazardous waste.

The definition of laboratory should be based on its operational characteristics rather than on the type or size of equipment or apparatus present. These characteristics could include a workplace:

- Where relatively small quantities of chemicals are used on a non-production basis,
- Multiple chemical procedures or chemicals are used, and
- Processes or procedures are undertaken by or under the supervision of qualified laboratory personnel.

**Contact Information:**

**Caitlyn Waller, Acting President**

Bay Area Bioscience Center  
651 Gateway Blvd., Suite 1145  
South San Francisco, CA 94080  
(650)-871-7101  
cwaller@baybio.org

**Denise Kato, Senior Env. Engineer**

Varian Medical Systems  
3100 Hansen Way, M/S F-095  
Palo Alto, CA 94304  
(650)-424-5812  
denise.kato@varian.com